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Technical Electronic Product Radiation Safety Standards Committee; Recharter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration announces the rechartering of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), by the Commissioner of Food and Drugs or designee. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (5 U.S.C. App. 2).

DATES: The new charter for this committee will extend to December 24, 1994.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 12420 Parklawn Dr., Rockville MD 20857, 301–443–2765.

Dated: January 21, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–3046 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0491]

Manna Pro Corp.; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Manna Pro Corp. The NADA provides for the use of a nicarbazin Type A article for making tylosin Type C chicken feeds. The sponsor requested the withdrawal of approval.

EFFECTIVE DATE: February 19, 1993.

FOR FURTHER INFORMATION CONTACT: Vitolis E. Vengris, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8749.

SUPPLEMENTARY INFORMATION: Manna Pro Corp., P.O. Box 11851, Fresno, CA 93775, is the sponsor of NADA 10–175, which provides for the use of a nicarbazin Type A article for making tylosin Type C chicken feeds. In its letter dated October 9, 1992, the sponsor requested that FDA withdraw approval of the NADA because the product is no longer marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 10–175 and all supplements and amendments thereto is hereby withdrawn, effective February 19, 1993.

Dated: January 28, 1993.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93–3048 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92F–0475]

SCM Chemicals; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that SCM Chemicals has filed a petition proposing that the food additive regulations be amended to provide for the safe use of phosphorylated tall oil fatty acids as pigment dispersants in polymeric films intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 3B4350) has been filed by SCM Chemicals, c/o 1100 G St. NW., Washington, DC 20001. The petition proposes to amend the food additive regulations to provide for the safe use of phosphorylated tall oil fatty acids as pigment dispersants in polymeric films intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: January 13, 1993.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–3049 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0499]

Lyphomed, Division of Fujisawa USA, Inc.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice of withdrawal of 10 Abbreviated New Drug Applications that appeared in the Federal Register of January 7, 1993 (58 FR 3027). The document was published with an incorrect date of signature. This document corrects that error.

SUPPLEMENTARY INFORMATION: In FR Doc. 93–242, appearing on page 3027, in the Federal Register of January 7, 1993, the following correction is made: On page 3028, in the first column, the date line that appears above the signature, which now reads "December 15, 1991." is corrected to read "December 15, 1992."

Dated: January 29, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–3047 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92E–0427]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZEBETA®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZEBETA® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term

Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZEBETA® (bisoprolol fumarate). ZEBETA® is indicated in the management of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZEBETA® (U.S. Patent No. 4,258,062) from E. Merck GmbH, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated November 13, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZEBETA® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZEBETA® is 2,874 days. Of this time, 1,778 days occurred during the testing phase of the regulatory review period, while 1,096 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* September 19, 1984. The applicant claims September 16, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 19, 1984, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* August 1, 1989. The applicant claims July 28, 1989, as the date the new drug application (NDA) for ZEBETA® (NDA 19–982) was filed. However, FDA records indicate that NDA 19–982 was submitted on August 1, 1989.

3. *The date the application was approved:* July 31, 1992. FDA has verified the applicant's claim that NDA 19–982 was approved on July 31, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 12, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 9, 1993, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–3050 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92E–0471]

Determination of Regulatory Review Period for Purposes of Patent Extension; Suprane™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Suprane™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the